IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCTS LIABILITY LITIGATION

MDL NO. 2:08-md-01968

THIS ORDER RELATES TO ALL CASES

PRETRIAL ORDER #33
(Memorandum Opinion and Order re Motions to Dismiss)

Pending are the motions to dismiss filed by Mylan Inc., Mylan Pharmaceuticals Inc., Mylan Bertek Pharmaceuticals Inc., and UDL Laboratories, Inc. ("Mylan Defendants") relating to Counts One, Two and Three of the Master Consolidated Complaint ("master complaint") [Docket 100] and the motions to dismiss filed by all Defendants relating to Counts Five and Eighteen [Docket 102 and 105]. For the reasons that follow, I **DENY** the Mylan Defendants' motion to dismiss Count One and Defendants' motion to dismiss Count Five. I also **DENY WITHOUT PREJUDICE** the Mylan Defendants' motion to dismiss Counts Two and Three and Defendants' motion to dismiss Count Eighteen.

I.

Defendants Actavis Totowa, LLC ("Actavis Totowa"), Mylan Bertek Pharmaceuticals, Inc., and UDL Laboratories, Inc., are citizens respectively of New Jersey, Delaware, Texas, and Illinois. Defendants Actavis, Inc., and Actavis Elizabeth, Inc., are citizens of Delaware. Plaintiffs allege those defendants manufactured, marketed, tested, promoted, sold and/or distributed Digitek® ("Digitek®" or "Digoxin" interchangeably). Defendants Mylan, Inc., and Mylan Pharmaceuticals, Inc., are respectively citizens of Pennsylvania and West Virginia. Plaintiffs allege those defendants

marketed, promoted, sold and/or distributed Digoxin. Mylan Pharmaceuticals, Inc., is also alleged to have distributed Digitek® (Digoxin) through its affiliates, Mylan Bertek Pharmaceuticals, Inc. and UDL Laboratories, Inc..

Digitek® is the brand-name of a cardiac glycoside, a compound affecting the myocardium of the heart. The drug is widely used to treat various heart conditions, including atrial fibrillation, atrial flutter, and heart failure that are uncontrolled by other medications. The United States Food and Drug Administration ("FDA") approved the drug with a certain level of the active ingredient, in the following dosages: (1) Digitek® (Digoxin tablets, USP) 0.125mg, and (b) Digitek® (Digoxin tablets, USP) 0.250 mg. The approved quantities are important because Digitek® has a narrow therapeutic index. Specifically, there is a limited margin between effectiveness and toxicity. An excessive dose of the active ingredient can cause result in serious health problems and death.

The plaintiffs allege that some of the Digitek® at issue in this action was, among other things, designed and manufactured at a plant in Little Falls, New Jersey ("Little Falls facility"), owned by one or more of the defendants. On or about August 15, 2006, the FDA issued a letter warning to the defendants through Actavis Totowa, LLC, for failing to file periodic safety reports from the Little Falls facility ("August 2006 Warning Letter"). The FDA cautioned that the defendants, through Actavis Totowa, LLC, had violated federal adverse medical event reporting obligations, marketed drugs without proper clearance, and caused at least twenty-six (26) adverse drug experiences ("ADEs") by failing to submit periodic safety reports. The August 2006 Warning Letter also noted an FDA inspection in early 2006 that revealed six potentially serious and unexpected adverse drug events dating back to 1999 for products, including Digoxin, that were not properly reported to the agency. The plaintiffs additionally allege that the defendants, through

Actavis Totowa, LLC, were alerted that they were (1) not properly investigating serious and unexpected ADEs, (2) not adequately reviewing ADE information, (3) failing to develop proper procedures for surveillance, receipt, evaluation and reporting of ADEs, and (4) failing to file periodic safety reports which resulted in the twenty-six (26) unreported ADEs.

On or about February 1, 2007, the FDA issued a Revised Warning Letter to the defendants through Actavis Totowa ("Revised Warning Letter"). It cited "significant deviations from the current Good Manufacturing Practice ['cGMP'] regulations." This likely accounts for the plaintiffs' allegation that the defendants' manufacturing, production, testing and inspection processes did not meet the then-current cGMP regulations found in 21 C.F.R. §§ 210 and 211. The cGMP regulations describe the methods, controls, equipment, and facilities that must be in place for drug manufacturing operations. The regulations serve to ensure consumer safety and a drug's consistency with its purported identity, strength, quality, and purity.

The plaintiffs allege that the deviations resulted in the adulteration of drugs manufactured by the defendants, and were observed by the FDA, during inspections on July 10 and August 10, 2006. According to the FDA's Revised Warning Letter:

> Significant deficiencies were found in the operations of your firm's quality control unit, and as a result there is no assurance that many drug products manufactured and released into interstate commerce by your firm have the identity, strength, quality and purity that they purport to possess.

(Master Compl. ¶ 29).

On August 10, 2006, the deviations were presented to Actavis Totowa on an FDA-483 ("List of Inspections").

The Revised Warning Letter also cited deficiencies in the operations of the quality control unit, which included instances where the unit failed to adequately investigate and resolve laboratory

deviations and out-of-specification test results for drug products. Specifically, according to the Revised Warning Letter:

> Our investigators observed numerous instances where the quality control unit failed to adequately investigate and resolve laboratory deviations and out-of-specification test results involving drug products that ultimately were released for distribution into interstate commerce. Additionally, our investigators uncovered out-of-specification test results in laboratory raw data that were not documented in laboratory notebooks, and found that products were released based on retesting without any justification for discarding the initial out-of-specification test results.

(Master Compl. ¶ 31).

The Revised Warning Letter also stated that analysts did not always document the preparation and testing of samples at the time they were performed:

> Master and batch production and control records were found to be deficient in that they did not include complete procedures for documenting the collection of samples. Although your firm's procedures require the collection of in-process blend uniformity samples of three times the weight of finished product tablets or capsules, master production records do not require, and batch records do not contain, documentation that the samples are being collected accordingly.

(Master Compl. ¶ 32).

The FDA also cited a failure to assure the accuracy of the input and outputs from a system used to run the high-performance liquid chromatography testing during drug analysis. Other deficiencies cited by the FDA in the Revised Warning Letter include: (1) a failure of the quality control unit to recognize that some tablets did not meet in-process specifications; (2) inconsistent documentation of failures to meet in-process specifications during tablet compression operations and failure to show that process deviations were promptly corrected to avoid releasing out of specification tablets; (3) a lack of adequate procedures for conducting bulk product holding time studies; (4) a failure to identify and control rejected in-process materials; (5) inadequate qualification of select equipment; and (5) a failure to establish and follow written procedures for

maintaining manufacturing equipment.

An example found in the Revised Warning Letter provides as follows concerning Actavis Totowa's manufacturing processes:

> Your firm's cleaning validation studies were found to be inadequate and, as a result, there was no assurance that equipment is adequately cleaned between the manufacture of different drug products. [21 CFR 211.67(b)] For example: a) Cleaning validation was performed for the process trains without evaluating for sample recovery for numerous products, including: . . . Digoxin Tablets, USP, 0.25mg.
>
> [W]e are concerned about the quality of drug products that have been released from your facility under the serious lack of cGMP controls found during the inspection. Your response provides no assurance that the records and conditions of manufacture and testing of each such lot of drug products released and marketed by your firm will be evaluated to assure that the released drug products have their appropriate identity, strength, quality and purity.

(Master Compl. ¶ 35).

As a result of the inspection findings, the defendants, through Actavis Totowa, were allotted 15 working days to provide a written listing of all unexpired, released lots of finished drug products associated with any out-of-specification test results during manufacture. Additionally, the FDA ordered a description of the actions taken to ensure that lots were suitable for release.

A Class I Recall of a drug is instituted only when "there is a reasonable probability that the use or exposure to a violative product will cause serious adverse health consequences or death." On or about April 25, 2008, the FDA announced a Class I Recall of all lots of Bertek and UDL Laboratories Digitek® (Digoxin) ("recalled Digitek® (Digoxin)"). The Class I recall stated as follows:

> Digitek (Digoxin Tablets, USP): Audience: Cardiologists, family physicians, pharmacists, other healthcare professionals, patients [Posted 04/28/2008] Actavis Totowa LLC notified healthcare professionals of a Class I nationwide recall of all strengths of Digitek, a drug used to treat heart failure and abnormal heart rhythms.

> The products are distributed by Mylan Pharmaceuticals Inc., under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label- The product is being recalled due to the possibility that tablets with double the appropriate thickness may contain twice the approved level of active ingredient. The existence of double strength tablets poses a risk of digitalis toxicity in patients with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Several reports of illnesses and injuries have been reported. Patients should contact their healthcare professional with questions. [April 25, 2008 - Press Release - Actavis Totowa, LLC]

(Master Compl. ¶ 38).

The plaintiffs allege that the Recalled Digitek® (Digoxin) is an adulterated drug. They also contend that its label and packaging are misbranded. The defendants are charged with having failed to inform the medical community and the public, including the plaintiffs, of the following material items:

1. How many and which lots of Digitek® (Digoxin) contained amounts of unapproved Digoxin;

2. How long the defendants manufactured and produced the recalled Digitek® . . . and how long the adulterated drug was supplied, sold, distributed, and released into the stream of commerce;

3. How many reports of illness and injuries have been received; and

4. The nature and extent of the reports of illness and injuries that were received.

The plaintiffs allege that these failures are consistent with the safety violations which led the FDA to issue the August 2006 Warning Letter and their failure to satisfy the cGMP regulations, including:

1. Deviating, without written justification, from their own written specifications, test procedures, and laboratory mechanisms, 21 C.F.R. §211.160(a);

2. Failing to establish the accuracy, specificity, and reproducibility of the test methods they employed, 21 C.F.R. §211.165(d);

3. Maintaining incomplete laboratory records of all testing data, 21 C.F.R. §

211.194(a)(4);

4. Failing to verify the suitability of all testing methods used under actual conditions of use, 21 C.F.R. §211.194(a)(2);

5. Failing to investigate unexplained out-of-specification testing results for drugs, 21 C.F.R. §211.192;

6. Failing to follow the defendants' own written stability testing program, 21 C.F.R. § 211.166(a);

7. Failing to record and justify deviations from the defendants' own written production and process control procedures, 21 C.F.R. §211.100(b) 12

8. Failing to examine and test samples to ensure that in-process materials conform to their specifications, 21 C.F.R. §211.110(b);

9. Failing to follow defendant's own written quality control procedures, 21 C.F.R. §211.22(d);

10. Failing to ensure that all data was reviewed and laboratory deviations were fully investigated and resolved prior to the release of drugs into commercial distribution, 21 C.F.R. §211.22(a);

11. Failing to have laboratory controls sufficient to ensure that components, in-process materials, and finished drug products have the appropriate standards of identify, strength, quality, and purity and conform to their written specifications, 21 C.F.R. §211.160(b); and

12. Failing to reject products that do not meet established standards or specifications and any other relevant quality control criteria, 21 C.F.R. §211.165(f).

Noting the "serious manufacturing practice, quality assurance and product safety issues with the production of Digitek® . . . as well as other products produced, manufactured, tested, marketed, distributed and sold or otherwise placed into the stream of commerce by Defendants[,]" the plaintiffs further allege that the Class-I recall for all-lots, all-doses of Digitek® bearing the defendants' labels resulted in the stoppage of production lines and the shuttering of the Little Falls plant.

The plaintiffs charge that the defendants, during the events outlined above, have "repeatedly

emphasized their reputations for quality manufacturing in publically available corporate documents and corporate run websites . . . and under-reported, underestimated and/or downplayed the serious dangers and the defective nature of Digitek® . . . ." (Master Compl. ¶¶ 46-47). The plaintiffs further allege that the defendants "have a history of [(1)] releasing drug products for public consumption that have been adulterated or misbranded . . . [(2)] . . . failing reliably to establish the identity, strength, quality and purity of drug products they release for public consumption . . . [and (3)] failing adequately to investigate and document test results on their drug products. (*Id.* at 48-50).

The plaintiffs' factual allegations conclude with the following representations concerning the defendants' omissions:

> The defendants are drug companies, that upon information and belief, engaged in the marketing, design, development, manufacture, production, processing, compounding, formulating, testing, sale, labeling, packaging, dosing, advertising, promotion, supplying, releasing and/or distribution of Digitek® . . . tablets with amounts of the active ingredient that was not consistent among Digitek® . . . tablets and amounts of the active ingredient that was inconsistent with the dose on the Digitek® . . . label. . . . At all times relevant to this action, Defendants knew, and/or had reason to know that the recalled Digitek® . . . tablets were not safe for the patients for whom the drug was prescribed because inconsistent or excess does of Digoxin can cause serious medical problems, Digoxin overdose, Digitalis toxicity and, in certain patients, catastrophic injuries and death. . . . Defendants failed to adequately warn users of the defective drug of its unreasonably dangerous characteristics due to the inconsistent and/or excess levels of active ingredient the drug contained.

(*Id.* at 51-53).

The filing of various civil actions in state and federal courts across the country followed the recall, in which plaintiffs claimed injuries from alleged exposure to defectively manufactured Digitek®. On August 13, 2008, the Judicial Panel on Multidistrict Litigation entered an order establishing a multidistrict litigation ("MDL") proceeding in this District consolidating federal Digitek® related actions for joint case management. In Pre-trial Order # 10, dated January 29, 2009,

the court directed the filing of a Master Complaint. The Master Complaint filed on February, 9, 2009, alleges the following claims:

Count One: Failure to Warn and Instruct
Count Two: Manufacturing Defect
Count Three: Design Defect
Count Four: Negligence
Count Five: Negligence *per Se*
Count Six: Breach of Implied Warranty
Count Seven: Breach of Express Warranty
Count Eight: Negligent Misrepresentation
Count Nine: Intentional Misrepresentation
Count Ten: Fraud
Count Eleven: Constructive Fraud
Count Twelve: Violation of the WVCCPA
Count Thirteen: Other UTPA Violations
Count Fourteen: Wrongful Death
Count Fifteen: Survival Action
Count Sixteen: Medical Monitoring
Count Seventeen: Unjust Enrichment
Count Eighteen: Medicare MSP Liability
Count Nineteen: Loss of Consortium

At the conclusion of Counts One, Two and Three, the plaintiffs allege that "[a]s a direct and proximate result of Defendants' acts and omissions, Plaintiffs have sustained severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial." (Master Compl. at ¶¶ 65, 73, and 81. Count Five alleges that "[a]s a direct and proximate result of Defendants' negligent, reckless, willful, wanton and grossly negligent acts and omissions" the same types of losses occurred. *(Id.* at 97). Count Eighteen, previously quoted in full, contains allegations of personal injury claims and "expenditures resulting from their injuries suffered in connection with the recalled Digitek (Digoxin)." *(Id.* at 175).

On April 20, 2009, the Mylan Defendants moved to dismiss Counts One, Two and Three, and all of the defendants moved to dismiss Counts Five and Eighteen. Responses were received on May 19, 2009 and replies on June 2, 2009.

II.

A. Governing Standard

Federal Rule of Civil Procedure 8(a)(2) requires that a pleader provide "a short and plain statement of the claim showing . . . entitle[ment] to relief." Fed. R. Civ. P. 8(a)(2); *Erickson v. Pardus*, 127 S. Ct. 2197, 2200 (2007). Rule 12(b)(6) correspondingly permits a defendant to challenge a complaint when it "fail[s] to state a claim upon which relief can be granted . . . ." Fed. R. Civ. P. 12(b)(6).

The required "short and plain statement" must provide "'fair notice of what the . . . claim is and the grounds upon which it rests.'" *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1964 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957), *overruled on other grounds, Twombly*, 127 S. Ct. at 1969)); *see also Anderson v. Sara Lee Corp.*, 508 F.3d 181, 188 (4th Cir. 2007). Additionally, the showing of an "entitlement to relief" amounts to "more than labels and conclusions . . . ." *Twombly*, 127 S. Ct. at 1965. It is now settled that "a formulaic recitation of the elements of a cause of action will not do." *Id.*; *Giarratano v. Johnson*, 521 F.3d 298, 304 (4th Cir. 2008).

The complaint need not, however, "make a case" against a defendant or even "forecast evidence sufficient to prove an element" of the claim. *Chao v. Rivendell Woods, Inc.*, 415 F.3d 342, 349 (4th Cir. 2005) (quoting *Iodice v. United States*, 289 F.3d 270, 281 (4th Cir. 2002)). Instead, the opening pleading need only contain "[f]actual allegations . . . [sufficient] to raise a right to relief above the speculative level." *Twombly*, 127 S. Ct. at 1965; *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009)(noting the opening pleading "does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation."). Stated another way,

the complaint must allege "enough facts to state a claim to relief that is plausible on its face." *Id.* at 1974; *Giarratano*, 521 F.3d at 302. The recent decision in *Iqbal* provides some guiadance concerning the plausibility requirement:

> A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.' "
>
> Rule 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era, but it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions. . . . Determining whether a complaint states a plausible claim for relief will, as the Court of Appeals observed, be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged-but it has not "show[n]"-"that the pleader is entitled to relief."
>
> In keeping with these principles a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth. While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.

Iqbal, 129 S. Ct. at 1949-50 (citations omitted).

As noted in *Iqbal*, the Supreme Court has consistently interpreted the Rule 12(b)(6) standard to require a district court to "'accept as true all of the factual allegations contained in the complaint . . . .'" *Erickson*, 127 S. Ct. at 2200 (quoting *Twombly*, 127 S. Ct. at 1965); *see also South Carolina Dept. of Health And Environmental Control v. Commerce and Industry Ins. Co.*, 372 F.3d 245, 255 (4th Cir. 2004) (quoting *Franks v. Ross*, 313 F.3d 184, 192 (4th Cir. 2002)). The court is additionally required to "draw[] all reasonable . . . inferences from those facts in the plaintiff's favor

. . . ." *Edwards v. City of Goldsboro*, 178 F.3d 231, 244 (4th Cir. 1999).

As a further overlay to this deferential standard, MDL courts have observed generally that a "master complaint should not be given the same effect as an ordinary complaint. Instead, it should be considered as only an administrative device to aid efficiency and economy." *See In re Propulsid Products Liability Litig.*, 208 F.R.D. 133, 142 (E.D. La. 2002); *see also In re Vioxx Products Liability Litig.*, 239 F.R.D. 450, 454 (E.D. La. 2006) (noting that a master complaint is simply "an administrative device used to aid efficiency and economy and, thus, should not be given the status of an ordinary complaint."); *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 56 (D.N.J. 2009)("In the absence of . . . consent, the majority of courts treat consolidated complaints filed in multi-district litigations as a procedural device rather than a substantive pleading with the power to alter the choice of law rules applicable to the plaintiffs' claims."); *Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 489 F. Supp.2d 932, 936 (D.C. Minn. 2007) ("The transfer under [28 U.S.C.] § 1407, even after the filing of an amended complaint, is only a change in courtrooms. Consolidation of a master complaint is merely a procedural device designed to promote judicial economy, and, as such, it does not affect the rights of the parties in separate suits.").

The administrative nature of a master complaint and its focus on facilitating management of the litigation, as opposed to being a primary operative pleading, has been considered in analyzing the motions to dismiss. Since it is uncertain how a master complaint should be treated when it is challenged via Rule 12(b)(6), the document has been read and construed at this point in the litigation in light of its procedural purpose.

B. Count One - Failure to Warn

The Mylan defendants claim it has not been alleged that they, as distributors, knew or had reason to know of the existence of a manufacturing defect prior to the recall. The Mylan Defendants

further contend that they cannot be held liable for a failure to warn because there are no instructions or warnings that could have made Digitek® safe for consumers under the alleged circumstances.

The Mylan defendants are correct that the master complaint lacks detailed factual allegations respecting their specific knowledge of a manufacturing defect. It does allege though that all of the defendants knew generally of a manufacturing defect and that they failed to act. Paragraphs 51-53, quoted above, are illustrative. (*See*, *e.g.*, ¶¶ 54-63).[1] The plaintiffs contend in the master complaint that, among other alleged misdeeds, (1) the Mylan defendants were involved in multiple cases of adverse drug events, (2) a number of these potentially serious and unexpected events were related to products including Digoxin, (3) Digoxin was the subject of multiple advisory letters from the FDA, foregoing an ultimate recall of Digitek®, which would have been directed, at least in part, to the Mylan defendants, and (4) the Mylan defendants failed to appropriately inform the medical community and the public, including the plaintiffs, of (a) how many and which lots of Digitek® contained amounts of unapproved Digoxin, (b) how long the recalled Digitek® was manufactured, produced, supplied, sold, distributed, and released into the stream of commerce, and (c) the number, nature and extent of the reports of illness and injuries that had been received.

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[1]The Mylan Defendants rely upon *Bryson v. Gonzales*, 534 F.3d 1282 (10th Cir. 2008), for the proposition that a generic allegation aimed at multiple defendants does not allege facts sufficient to give notice or establish a plausible right to recovery. The decision in *Bryson* involved a pleading by an inmate convicted of sexual assault who spent 19 years in jail until exonerated by DNA evidence. He sued a host of officials, including a police chemist, a district attorney, and a former police chief, alleging that they falsely procured his original conviction and then prevented him from obtaining access to the DNA evidence. Among other factors readily distinguishing *Bryson* from this action is the court of appeals' observation that follows:

> "In § 1983 cases, defendants often include the government agency and a number of government actors sued in their individual capacities. Therefore it is particularly important in such circumstances that the complaint make clear exactly who is alleged to have done what to whom, to provide each individual with fair notice as to the basis of the claims against him or her, as distinguished from collective allegations against the state."

Id. at 1290 (citation and quoted authority omitted).

In the Count One the plaintiffs further outline that (1) Digitek® was in an unsafe, defective and inherently dangerous condition which was unreasonably dangerous to its users; (2) the labeling, packaging and warnings were insufficient to alert consumers, including the plaintiffs, of the dangerous risks and reactions associated with the recalled Digitek®; (3) the plaintiffs are alleged to be in a class of persons that the defendants, including Mylan defendants, should have been considered to be subject to harm caused by Digitek®'s defective nature; (4) the defendants knew, or should have known, through quality control procedures, testing, adverse event reporting or otherwise that Digitek® was in a defective condition and the label, warnings, and dosage information provided with the recalled Digitek® were not accurate and (5) the defendants failed to provide adequate and timely warnings or instructions regarding Digitek®. (Master Compl. at ¶¶ 57-61). Also pled is the Mylan defendants' default on its continuing duty to warn the plaintiffs of the dangers associated with the recalled Digitek® and the assertion that if they had done so, the plaintiffs would not have used it. *(Id.* at 63-64).

In applying *Twombly*'s plausibility standard, each of these factual allegations is treated as entirely accurate, however true or misguided a fact finder might ultimately find them to be. Plaintiffs allege and infer that as distributors of the drug which was, at least in part, the subject of the FDA warning letters and the eventual recall, it is plausible the Mylan Defendants knew or had reason to know of the alleged manufacturing defects, and then failed to appropriately warn and instruct the plaintiffs. Additionally, the Mylan Defendants concede that a party may be held liable for failure to warn even if it only has "constructive knowledge" of a product's defective nature. (*See, e.g.*, Memo. in Supp. of Mot. to Dis. Cts. One, Two, and Three at 3).

Accordingly, the Master Complaint provides the Mylan Defendants adequate notice of the claims pled against them and, accepting the associated factual allegations as true, a plausible claim

for relief is alleged in Count One. I **DENY** the Mylan Defendants' motion to dismiss Count One.[2]

C. Counts Two and Three - Product Liability - Manufacturing and Design Defect

The Mylan defendants next assert that Counts Two and Three should be dismissed because distributors that did not participate in a product's design or manufacture cannot be held liable for defects that arose in the product at those two stages of the manufacturing process. Plaintiffs contend that the law is to the contrary in a majority of jurisdictions. Both parties rely upon case law not dealing with allegations of a defective prescription drug. The entirety of the briefing on the point spans just a few pages.

The *Restatement (Third) of Torts* speaks to the liability of manufacturer and distributor defendants involved in the production and sale of defective prescription drugs. Section 6(e) provides as follows:

> (e) A retail seller or other distributor of a prescription drug or medical device is subject to liability for harm caused by the drug or device if:
>
> > (1) at the time of sale or other distribution the drug or medical device contains a manufacturing defect as defined in § 2(a); or
> >
> > (2) at or before the time of sale or other distribution of the drug or medical device the retail seller or other distributor fails to exercise

[2]The Mylan Defendants assert in the alternative that no instructions or warnings could have made Digitek® safe under the circumstances. They appear to contend that if it is impossible to cure a potential defect, such as double thickness tablets mistakenly created, which cannot be rendered reasonably safe for consumers through adequate warnings, that the Mylan defendants should be exonerated as a matter of law as to Count One. No case law is cited for the proposition and Defendants did not further address the argument in their reply. I do not deem this contention to warrant dismissal of Count One at this early stage. Discovery will better illuminate the timing and substance of the knowledge possessed by the Mylan defendants, and the adequacy of any warnings they should have offered in light of those considerations.

reasonable care and such failure causes harm to persons.

Restatement (Third) of Torts: Prod. Liab. § 6 (1998). The commentary to section 6(e) provides as follows:

> *h. Liability of retail seller of prescription drugs and medical devices for defective designs and defects due to inadequate instructions or warnings.* The rule governing most products imposes liability on wholesalers and retailers for selling a defectively designed product, or one without adequate instructions or warnings, even though they have exercised reasonable care in marketing the product. See § 1, Comment e, and § 2, Comment o. Courts have refused to apply this general rule to nonmanufacturing retail sellers of prescription drugs and medical devices and, instead, have adopted the rule stated in Subsection (e). That rule subjects retailers to liability only if the product contains a manufacturing defect or if the retailer fails to exercise reasonable care in connection with distribution of the drug or medical device. In so limiting the liability of intermediary parties, courts have held that they should be permitted to rely on the special expertise of manufacturers, prescribing and treating health-care providers, and governmental regulatory agencies. They have also emphasized the needs of medical patients to have ready access to prescription drugs at reasonable prices.

Restatement (Third) of Torts: Prod. Liab. § 6 (1998) (comment.).

The Restatement approach casts doubt on a non-manufacturing party's liability for design defects, at least where that down-the-line entity is not negligent. *See* 1 David G. Owen *et al.*, *Madden & Owen on Products Liability* § 5:12 (3d ed. 2009) (noting section "6(e) provides that retail sellers are subject only to negligence liability for selling such products containing design or warnings defects."); *see* 3 J.D. Lee & Barry Lindahl, *Modern Tort Law: Liability and Litigation* § 27:45 (2d ed. 2009). At the same time, the Restatement approach has not been uniformly accepted. *See* 5 Roxanne Barton *et al.*, *Litigating Tort Cases* § 60:23 (2009) ("Indeed, the Wisconsin court declined to adopt the new Restatement, noting that the new provision had been the subject of controversy, and that it had even been referred to by various commentators as 'a wish list from manufacturing America' and a vehicle for tort reform.").

The unsettled and apparently complex nature of the law of the fifty states aside, a different issue also precludes dismissal at this juncture. The Mylan defendants contend that "[p]laintiffs are aware that [the] Mylan Defendants did not participate in the design or manufacture of Digitek®." (Defs.' Memo. in Supp. at 6). At the same time, they candidly concede that the matter is "not always consistently pleaded . . . ." *Id.* The exact relationship between the defendants, their knowledge of material events, the timing of their receipt of that knowledge, and the impact those fact intensive questions may have on the application of the unsettled, governing law all counsel in favor of allowing the challenged Counts to proceed to discovery.

At the conclusion of that process, the parties may brief the matter anew at summary judgment, supported by a multi-state survey of the governing law. I can then best determine whether the matter is suitable for coordinated resolution. Accordingly, I **DENY** without prejudice the Mylan Defendants' motion to dismiss Counts Two and Three.

D. Count Five - Negligence Per Se

Count Five alleges a claim for negligence *per se*. Plaintiffs cite the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, along with unstated "related amendments, codes and federal regulations provided there under, and other applicable laws, statutes, and regulations" as the legislatively imposed standard of care supporting their negligence *per se* claim (Master Compl.¶ 91). After alleging that they reside within the class of individuals that the FDCA and the other unnamed "statutes and regulations" are designed to protect, they further contend as follows

> Defendants' acts constitute an adulteration and misbranding as defined by the . . . [FDCA] and the regulations promulgated there from and constitutes a breach of duty under the theory of negligence *per se*.
>
> Defendants' manufacturing, production, testing and inspection processes are not good manufacturing processes in violation of the . . . [FDCA] and the regulations

> promulgated therefrom and constitutes a breach of duty under the theory of negligence *per se*.
>
> The acts and omissions set forth above, demonstrate that Defendants failed to meet the standard of care set by the applicable statutes and regulations, which were intended for the benefit of individuals such as Plaintiffs making Defendants negligent *per se*.

(Master Compl. ¶¶ 92-95).

The defendants initially moved to dismiss Count Five as an improper private FDCA enforcement action. In their response, Plaintiffs concede a private right of action does not exist under the FDCA. They clarified, however, that Count Five was solely based in negligence, with the FDCA merely serving as one component of the violations of law in which they claim defendants engaged. In reply, the defendants persist in asserting the claim fails as a matter of law.

The analysis is controlled by *Talley v. Danek Medical, Inc.*, 179 F.3d 154 (4th Cir. 1999). In *Talley*, plaintiff had a medical device implanted. She asserted that the device was used for a purpose not approved by the FDA. The district court dismissed the action at summary judgment. Plaintiff asserted on appeal that genuine issues of material fact remained over whether defendant "violated the . . . [FDCA] and that a violation of the FDCA constitutes negligence *per se* in Virginia." *Id.* The court of appeals, in an opinion authored by Judge Niemeyer, first discussed generally the nature of a negligence *per se* claim:

> [I]n negligence *per se* cases, the courts "adopt as the standard of conduct of a reasonable man the requirements of a legislative enactment or an administrative regulation."
>
> An example illustrates the doctrine's application. If the statutory speed limit on a road is 35 m.p.h. and the defendant drives 40 m.p.h., causing him to collide with the plaintiff pedestrian and to injure her, the plaintiff may establish the breach element of her negligence claim *by pointing to the violation of the speed limit*. The defendant is barred from putting on evidence, specific to his situation, that driving at 40 mph. on that particular road was reasonable because *the "violation of the*

statute constitutes conclusive evidence of negligence."

Id. at 158.

The decision in *Talley* also observes that the negligence *per se* doctrine "is not a magic transforming formula that automatically creates a private right of action for the civil enforcement, in tort law, of every statute." *Id.* Instead, the claim substitutes a standard of care created by the legislature for one that would otherwise be created by the common law. There are also limits placed on the doctrine to assure that it does not become a means to practically create private rights of action for statutory violations. The decision in *Talley* recognizes at least two means for "cabin[ing]" the doctrine:

> First, not all statutory provisions dictate a standard of care, and therefore not all statutory violations can provide a basis for establishing negligence *per se*. Second, even when a statutory provision does specify a standard of care, a plaintiff must still prove the additional elements of duty, proximate causation, and injury to establish liability.

Id. at 159. A statute will be deemed not to define a standard of care where it only imposes an administrative requirement, "such as the [mandate] to obtain a license or to file a report to support a regulatory scheme . . . ." *Id.*

The plaintiff in *Talley* asserted a violation of 21 U.S.C. § 360e(a), which requires premarket approval for certain medical devices.[3] As noted, she asserted that premarket approval had not

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[3]Coincidentally, the plaintiff, as in this case, relied as well upon 21 U.S.C. § 331(a), which provides as follows:

> The following acts and the causing thereof are prohibited:
>
> > (a) The introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded.

(continued...)

occurred because the implanted device was used in a manner not approved by the FDA. The court of appeals explained why her theory could not support a negligence *per se* claim:

> Breach of the requirement not to misbrand a surgical nail[, as in the case of *Orthopedic Equipment Co. v. Eutsler*, 276 F.2d 455 (4th Cir. 1960),] is similar to a breach of a speed limit; each violates a specific and substantive standard of care that is intended to protect others. The holding in *Eutsler*, however, does not establish the principle that the simple failure to obtain approval of a device from the FDA, standing alone, can support a negligence per se claim. The administrative requirement that a given device be approved by the FDA before being marketed -- as opposed to a specific substantive requirement that a device be safe and effective -- is only a tool to facilitate administration of the underlying regulatory scheme. Because it lacks any independent substantive content, it does not impose a standard of care, the breach of which could form the basis of a negligence per se claim. Its breach is analogous to the failure to have a drivers license.

Id. at 161.

Unlike the mandate of section 360e(a), and the circumstances in *Talley*, Count Five, and section 331(a), speak to the breach of a clear cut statutory prohibition. Specifically, Congress has commanded drug manufacturers not to deliver in interstate commerce any misbranded drug. Plaintiffs have, in addition to other violations, specifically alleged misbranding. The statutory directive found in section 331(a) is not unlike the unadorned legislative prohibition on exceeding a certain speed on an interstate highway. The analogy is, in light of the analysis in *Talley*, fatal to defendants' Rule 12(b)(6) challenge to Count Five. Accordingly, I **DENY** the defendants' motion to dismiss Count Five.

E. Count Eighteen - Medicare Secondary Payer Act

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[3](...continued)
Id. The court of appeals does not appear to have separately discussed the suitability of this subsection to support a negligence *per se* claim.

The defendants assert that Count Eighteen fails to state a claim because (1) it lacks an allegation that plaintiffs are a "primary plan[,]" and (2) defendants have no responsibility for any Medicare payments to the plaintiffs. Aside from an additional paragraph incorporating prior allegations, the entirety of Count Eighteen reads as follows:

> In addition to their own personal injury claims, Plaintiffs, whose medical care costs arising from Digitek® (Digoxin) were paid in whole or in party by Medicare, bring this cause of action pursuant to the private cause of action provisions of the Medicare as Secondary Payer Statute [("MSP") 42 U.S.C. § 1395y(b)(3)(A)] to recover "double damages" of all Medicare expenditures resulting from their injuries suffered in connection with the recalled Digitek® (Digoxin).

(Master Compl. ¶ 175).

The United States Court of Appeals for the First Circuit recently explained the nature and workings of the MSP:

> Prior to 1980, Medicare generally paid for medical services whether or not the Medicare beneficiary also was covered by another health plan. The MSP statute, which was enacted in 1980 to reduce federal health care costs, makes Medicare the secondary payer for medical services provided to Medicare beneficiaries whenever payment is available from another primary payer.
>
> To that end, the MSP statute prohibits Medicare from making any payment to a beneficiary for medical expenses if "payment has been made, or can reasonably be expected to be made promptly (as determined in accordance with regulations) under . . . an automobile or liability insurance policy or plan (including a self-insured plan) or under no-fault insurance." Should Medicare determine that the primary insurer has not paid and that no prompt payment reasonably can be expected from the primary insurer, however, Medicare may pay the beneficiary up front, but such payment is conditioned on Medicare's right to reimbursement in the event that a primary plan later pays or is found responsible for payment of the item or service.
>
> To facilitate recovery of these conditional payments, the MSP . . . creates a private cause of action with double recovery to encourage private parties to bring actions to enforce Medicare's rights . . . .

United Seniors Ass'n, Inc. v. Philip Morris USA, 500 F.3d 19, 21-22 (1st Cir. 2007).

The Defendants primarily assert that their responsibility for any Medicare monies expended to treat plaintiffs must be judicially fixed before the MSP private right of action ripens, meaning Count Eighteen is premature. Plaintiffs assert that they are entitled to establish defendants liability under the MSP in the same action that would serve as the predicate to MSP liability. In the alternative, plaintiffs ask the court to bifurcate Count Eighteen until such time, if ever, that defendants' liability for plaintiffs' injuries is established.

To the extent it is not unanimous, the overwhelming weight of the case law has adopted the defendants' position. The United States Court of Appeals for the Eleventh Circuit recently observed as follows:

> Our conclusion that section 1395y(b)(3) does not create a private cause of action against alleged -- as opposed to proved -- tortfeasors whose responsibility for payment of medical costs has not been previously established is supported by three additional considerations. First, Plaintiffs' proposed interpretation of section 1395y(b)(3)(A) would drastically expand federal court jurisdiction by creating a federal forum to litigate any state tort claim in which a business entity allegedly injured a Medicare beneficiary, without regard to diversity of citizenship or amount in controversy. Second, under Plaintiffs' interpretation, an alleged tortfeasor that is sued under the MSP (instead of under state tort law) could not contest liability without risking the penalty of double damages: defendants would have no opportunity to reimburse Medicare after responsibility was established but before the penalty attached. Third, Plaintiffs' proposed interpretation would allow individuals acting as private attorney generals to litigate the state tort liability of a defendant towards thousands of Medicare beneficiaries -- as a predicate to showing MSP liability -- without complying with class action requirements. We are confident that, if Congress intended such radical innovations in jurisdiction, federal-state relations, and tort liability, it would have more clearly expressed its intent.

Glover v. Liggett Group, Inc., 459 F.3d 1304, 1309 (11th Cir. 2006); *see also*, *e.g.*, *Mason v. American Tobacco Co.*, 346 F.3d 36, 43 (2nd Cir. 2003)(observing that "[D]efendants are clearly correct when they assert that 'the trigger for bringing a MSP claim is not the pendency of a disputed tort claim, but the established obligation to pay medical costs pursuant to a pre-existing arrangement

to provide insurance benefits.'"); *National Committee to Preserve Social Sec. and Medicare v. Philip Morris USA Inc.*, 601 F. Supp.2d 505, 509 (E.D.N.Y. 2009) ("Little discussion is required, as the weight of authority is entirely with defendants. Indeed, each of the federal courts to have considered the questions raised here has rejected plaintiffs' view of the . . . [MSP].").

The precise issue raised by the defendants has, however, recently been presented for decision to the United States Court of Appeals for the Fourth Circuit in *Bio-Medical Applications of N.C., Inc. v. Brooks Food Group, Inc.*, No. 08-1819 (4th Cir. Jul. 29, 2008). Oral argument is scheduled for September 22, 2009. Pending the decision in *Brooks Food Group*, I **DENY WITHOUT PREJUDICE** defendants' motion to dismiss Count Eighteen.

III.

Based upon the foregoing analysis, I (1) **DENY** the Mylan Defendants' motion to dismiss Count One and Defendants' motion to dismiss Count Five, and (2) **DENY WITHOUT PREJUDICE** the Mylan Defendants' motion to dismiss Counts Two and Three and Defendants' motion to dismiss Count Eighteen.

The court **DIRECTS** the Clerk to file a copy of this memorandum opinion and order in 2:08-md-1968 which shall apply to each member Digitek-related case previously transferred to, removed to, or filed in this district, which includes counsel in all members cases up to and including civil action number 2-09-cv-875. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the

most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsd.uscourts.gov.

ENTER: August 3, 2009